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TRANSMITTAL FORM

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Total Number of Pages in This Submission

Application Number	09/830,300
Filing Date	July 5, 2001
First Named Inventor	Achim Berthold
Art Unit	1616
Examiner Name	Sharmila S. Gollamudi
Attorney Docket Number	RO0282US.RCE2 (#90568)

ENCLOSURES *(Check all that apply)*

- [X] Fee Transmittal Form
  - [X] Fee Attached
- [ ] Amendment/Reply
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [ ] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Reply to Missing Parts/ Incomplete Application
  - [ ] Reply to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Drawing(s)
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- [ ] Power of Attorney, Revocation Change of Correspondence Address
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  - [ ] Landscape Table on CD
- [ ] After Allowance Communication to TC
- [ ] Appeal Communication to Board of Appeals and Interferences
- [X] Appeal Communication to TC **(Appeal Notice, Brief, Reply Brief)**
- [ ] Proprietary Information
- [ ] Status Letter
- [X] Other Enclosure(s) (please Identify below):

Exhibits and return postcard receipt

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	D. Peter Hochberg Co., L.P.A.		
Signature			
Printed name	D. Peter Hochberg		
Date	April 20, 2006	Reg. No.	24,603

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Typed or printed name	Sean Mellino	Date	April 20, 2006

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Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

FEE TRANSMITTAL For FY 2006

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT	($)	500.00

Complete if Known	
Application Number	09/830,300
Filing Date	July 5, 2001
First Named Inventor	Achim Berthold
Examiner Name	Sharmila S. Gollamudi
Art Unit	1616
Attorney Docket No.	RO0282US.RCE2 (#90568)

METHOD OF PAYMENT (check all that apply)

☐ Check ☒ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): _____

☒ Deposit Account Deposit Account Number: 08-2441 Deposit Account Name: D. Peter Hochberg Co., L.P.A.

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

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FEE CALCULATION (All the fees below are due upon filing or may be subject to a surcharge.)

1. BASIC FILING, SEARCH, AND EXAMINATION FEES

Application Type	FILING FEES Fee ($)	FILING FEES Small Entity Fee ($)	SEARCH FEES Fee ($)	SEARCH FEES Small Entity Fee ($)	EXAMINATION FEES Fee ($)	EXAMINATION FEES Small Entity Fee ($)	Fees Paid ($)
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

2. EXCESS CLAIM FEES

Fee Description	Fee ($)	Small Entity Fee ($)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180

Total Claims _____ - 20 or HP = _____ x _____ = _____ Extra Claims / Fee ($) / Fee Paid ($)

HP = highest number of total claims paid for, if greater than 20.

Indep. Claims _____ - 3 or HP = _____ x _____ = _____ Extra Claims / Fee ($) / Fee Paid ($)

HP = highest number of independent claims paid for, if greater than 3.

Multiple Dependent Claims Fee ($) _____ Fee Paid ($) _____

3. APPLICATION SIZE FEE

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is $250 ($125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets _____ - 100 = _____ Extra Sheets / 50 = _____ Number of each additional 50 or fraction thereof (round **up** to a whole number) x _____ Fee ($) = 0.00 Fee Paid ($)

4. OTHER FEE(S)

Non-English Specification, $130 fee (no small entity discount) Fees Paid ($) _____

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SUBMITTED BY

Signature	D Hochberg	Registration No. (Attorney/Agent) 24,603	Telephone 216-771-3800
Name (Print/Type)	D. Peter Hochberg		Date April 20, 2006

This collection of information is required by 37 CFR 1.136. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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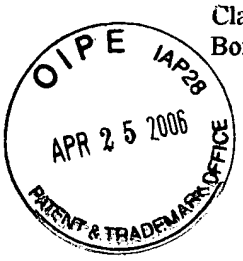

April 20, 2006
Date

Sean F. Mellino

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Achim Berthold
Serial No.	:	09/830,300 / Conf. No. 8251
Filing Date	:	July 5, 2001
Examiner / Group Art Unit	:	Sharmila S. Gollamudi / 1616
Title	:	Therapeutic System Containing an Active Substance for the Application on the Skin which Contains at least Two Polymerous Layers
Attorney File	:	RO0282US.RCE2 (#90568)
Technology Center	:	1600

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APPEAL BRIEF

Dear Sir:

This brief is in furtherance of the Notice of Appeal filed in this case on February 17, 2006 and received by the United States Patent and Trademark Office on February 21, 2006.

Enclosed is a Credit Card Payment Form authorizing a large entity charge of $500.00 to cover the fee for filing the brief in support of the appeal. Please charge any additional fees which may be required for this matter to Applicant's attorney's Deposit Account No. 08-2441 – D. Peter Hochberg Co., L.P.A.

Real Party in Interest:

The real party in interest is the assignee of the Applicant, LTS Lohmann Therapie-Systeme AG.

Related Appeals and Interferences:

None.

Status of Claims:

Claims 1-32 are canceled. Claims 33-43 are pending in the application. The rejection of claims 33-43 is being appealed.

Status of Amendments:

No further amendments have been filed subsequent to the Final Office Action which is dated October 19, 2005.

Summary of Claimed Subject Matter:

This invention relates to an active substance-containing therapeutic system for application to the skin. The system comprises at least two polymer-containing layers. The invention further relates to a manufacturing process for producing the active substance-containing therapeutic system having at least two polymer-containing layers.

The various layers which comprise the active substance-containing therapeutic system differ in their glass transition temperatures (Tg) and at least one of the layers is formed and arranged as an active substance reservoir. The layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system, thereby reducing cold flow.

The invention further includes a process for manufacturing the therapeutic system comprising the steps of laminating at least two polymer-containing layers upon one another. The polymer-containing layers may differ in their glass transition temperatures or may be the same.

One example of the system of the present invention, as shown in Figure 1 of the specification (a copy of Figure 1 is included with the "Evidence Appendix, Exhibit IV" for ease of reference), includes a backing layer, a polymer-containing matrix having a glass transition temperature (Tg1), a polymer-containing matrix having a glass transition temperature (Tg2), a polymer-containing matrix having a glass transition temperature (Tg1) and a detachable protective layer.

This of course is just one example and the present invention is not intended to be limited to this example. Since the present invention includes polymer-containing layers which may differ in their glass transition temperatures, then the aforementioned example

could be modified such that the third polymer-containing matrix has a glass transition temperature which is different from that of the first polymer-containing matrix. In this instance, the glass transition temperature would be defined as (Tg3).

The pharmaceutical preparation is an active substance-containing device which releases one or more medicinal agents at a predetermined continuous rate over a defined period of time to a defined site. It is known that the cohesion of an adhesive having high-viscous, permanent-adhesive polymer structure is decisively influenced by the glass transition temperature of the polymers employed.

Cold flow simply describes a property of a material whereby the affected materials start to flow during storage without having been subjected to special influences. Devices, such as transdermal therapeutic systems, often tend to show cold flow. This situation leads to the device becoming agglutinated with the primary packaging means while it is being stored which causes difficulty in removing the device from the packaging. An additional problem caused by cold flow is that after application, the patches tend to leave black margins, which are residues of adhesive, on the application surface which can be difficult to clean and/or remove.

The present invention provides a process for improving cohesion in order to achieve a clear reduction of the cold flow and leads to a high bioavailability of the active substances and auxiliary substances contained in the device. The device essentially comprises at least two polymer-containing layers each of which may differ or have the same glass transition temperatures. The layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system. Consequently, cold flow is reduced such that the problem with devices becoming

agglutinated with the primary packaging means during storage and leaving black edges on the application surface due to residue of adhesive is eliminated or at least significantly reduced.

Grounds of Rejection to be Reviewed on Appeal:

The following issues are present in the present appeal:

1. Was the rejection of claims 33-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement proper?

2. Was the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 6,063,838 (Patnode, *et al.*) under 35 U.S.C. §103(a) proper?

3. Was the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 5,023,084 (Chien, *et al.*) under 35 U.S.C. §103(a) proper?

Grouping of Claims:

This appeal should be decided with respect to claims 33, 34, 39, 40, 41, 42 and 43. Claims 33, 34, 39, 40, 41, 42 and 43 are the only independent claims in the case, and it follows that if the appeal overturns the final rejection of claims 33, 34, 39, 40, 41, 42 and 43, the respective remaining dependent claims would be allowed. It is therefore requested that the group of claims to be selected by the Board include claims 33, 34, 39, 40, 41, 42 and 43. The Applicant believes that claims 33-43 rise and fall together.

Argument:

The rejection of claims 33-43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 6,063,838 (Patnode, *et al.*) under 35 U.S.C. §103(a) and the rejection of claims 33-43 as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) by itself or in view of U.S. Patent No. 5,023,084 (Chien, *et al.*) under 35 U.S.C. §103(a) are improper and should be reversed.

Claim 33 recites a method for providing therapeutic applications in humane medicine. The method comprises the step of applying a therapeutically active substance-containing therapeutic system to living skin. The system comprises three layers, the first layer comprising a polymer having a glass transition temperature (Tg1), the second layer comprising a polymer having a glass transition temperature (Tg2) and the third layer comprising a polymer having a glass transition temperature (Tg3). The three layers are laminated on top of each other such that the second layer with Tg2 is located between the first and third layers. Regarding the respective glass transition temperatures, Tg2 is greater than Tg1 and Tg3. On the other hand, Tg1 and Tg3 may be either identical or different from each other. At least one of the layers of the system contains at least one therapeutically active substance. As described in the specification, the layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system for reducing cold flow.

Claim 34 recites an active substance-containing therapeutic system for application on the skin. The system comprises three polymer-containing layers, the first layer

comprising a polymer having a glass transition temperature (Tg1), the second layer comprising a polymer having a glass transition temperature (Tg2) and the third layer comprising a polymer having a glass transition temperature (Tg3). The three layers are laminated on top of each other such that the second layer having Tg2 is located between the first and third layers. Regarding the respective glass transition temperatures, Tg2 is greater than Tg1 and Tg3 while Tg1 and Tg3 may be either identical or different. At least one of the layers of the system contains at least one therapeutically active substance. As described in the specification, the layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system for reducing cold flow.

Claim 39 recites a process for manufacturing the therapeutic system as recited in claim 34. The process comprises laminating a first polymer-containing layer having Tg1 onto a second polymer-containing layer having Tg2, and then laminating a third polymer-containing layer having Tg3 onto the second layer. The three layers are laminated on top of each other such that the second layer having Tg2 is located between the first and third layers. Tg2 is greater than Tg1 and Tg3, and Tg1 and Tg3 may either be identical or different from each other. At least one of the layers of the system contains at least one therapeutically active substance. As described in the specification, the layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system for reducing cold flow.

Claim 40 recites a method for providing therapeutic applications in humane medicine, the method comprising the step of applying a therapeutically active substance-containing therapeutic system to living skin. At least one of the polymer-containing

layers is an active substance release rate-controlling layer. The three layers of the system include a first polymer-containing layer having Tg1, a second polymer-containing layer having Tg2, and a third polymer-containing layer having Tg3. The three layers are laminated on top of each other such that the second layer having Tg2 is located between the first and third layers. Tg2 is greater than Tg1 and Tg3, and Tg1 and Tg3 may be either identical or different from each other. At least one of the layers of the system contains at least one therapeutically active substance. As described in the specification, the layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system for reducing cold flow.

Claim 41 recites a method for providing therapeutic applications in humane medicine. The method comprises the step of applying a therapeutically active substance-containing therapeutic system to living skin. The three layers of the system include a first polymer-containing layer having Tg1, a second polymer-containing layer having Tg2, and a third polymer-containing layer having Tg3. The three layers are laminated on top of each other such that the second layer having Tg2 is located between the first and third layers. Tg2 is greater than Tg1 and Tg3 and Tg1 and Tg3 may be either identical or different from each other. At least one of the layers of the system contains at least one therapeutically active substance. The polymers having Tg1 and Tg2 are selected from the group consisting of polymers based on methacrylic acid and polymers based on polyacrylic acid esters. The polymer having Tg3 is selected from the group consisting of methacrylic acid esters. As described in the specification, the layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system for reducing cold flow.

Claim 42 recites an active substance-containing therapeutic system for application on the skin. The system comprises three polymer-containing layers. The three layers of the system include a first polymer-containing layer having Tg1, a second polymer-containing layer having Tg2, and a third polymer-containing layer having Tg3. The three layers are laminated on top of each other such that the second layer having Tg2 is located between the first and third layers. Tg2 is greater than Tg1 and Tg3, and Tg1 and Tg3 may be either identical or different from each other. At least one of the layers of the system contains at least one therapeutically active substance. The polymers having Tg1 and Tg2 are selected from the group consisting of polymers based on methacrylic acid and polymers based on polyacrylic acid esters. The polymer having Tg3 is selected from the group consisting of methacrylic acid esters. As described in the specification, the layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system for reducing cold flow.

Claim 43 recites a method for providing therapeutic applications in humane medicine. The method comprises the step of applying a therapeutically active substance-containing therapeutic system to living skin. At least one of the polymer-containing layers is an active substance release rate-controlling layer. The system comprises three polymer-containing layers. The three layers of the system include a first polymer-containing layer having Tg1, a second polymer-containing layer having Tg2, and a third polymer-containing layer having Tg3. The three layers are laminated on top of each other such that the second layer having Tg2 is located between the first and third layers. Tg2 is greater than Tg1 and Tg3 and Tg1 and Tg3 may be either identical or different from each other. At least one of the layers of the system contains at least one

therapeutically active substance. The polymers having Tg1 and Tg2 are selected from the group consisting of polymers based on methacrylic acid and polymers based on polyacrylic acid esters. The polymer having Tg3 is selected from the group consisting of methacrylic acid esters. As described in the specification, the layer(s) with the higher glass transition temperature(s) lead(s) to an improvement of the cohesion of the entire system for reducing cold flow.

The Examiner first states in the Final Office action dated October 19, 2005, on page 2, that the instant specification has support for three polymer-containing layers, as evidenced by Figure 1 in the specification. However, the Examiner maintains the position that the specification and Figure 1 only provide support for a system that has two layers with different glass transition temperatures rather than three, referencing Figure 1 and page 10 as support for this position. Consequently, the Examiner argues in the Final Office action that the recitation "the glass temperature Tg1 of the polymer of the first layer and the glass transition temperature Tg3 of the polymer of said third layer are identical *or different* (emphasis provided)" does not have any support in the specification since there is only support for the first layer and the third layer having identical glass temperatures. Therefore, the Examiner considers the limitation "different" to be new subject matter.

The Examiner next states in the Final Office action (on page 4) that claims 33-43 are rejected as being unpatentable over Otsuka, et al. by itself or in view of Patnode, et al. The Examiner argues that Otsuka, et al. teach a pressure sensitive adhering composite medicinal preparation to provide drug supply to the skin and that the composite comprises **at least** (emphasis provided) two layers, namely, **at least one** (emphasis

provided) pressure-adhering macromolecular substance layer and polymer layer adjacent to the macromolecular substance layer. The Examiner goes on to state that the polymer layer contains a polymer or copolymer that has a glass transition temperature (Tg) of not lower than -50 degrees Celsius, preferably -45 to +45 degrees Celsius. The Examiner ultimately argues that Otsuka, et al. teach every limitation of claims 33-43, except for the third layer.

In this regard, the Examiner argues that it would have been obvious to refer to Otsuka, et al. and incorporate a third polymer-containing layer, with motivation to do so lying in the teaching of Otsuka, et al. that the composite should contain *at least* (emphasis provided) two layers and in particular *at least one* (emphasis provided) macromolecular layer (Final Office action, page 6). The Examiner argues that if a skilled artisan followed the suggestion provided by Otsuka, et al. and utilized two macromolecular layers, that skilled artisan would arrive at the instant invention wherein the invention would have a macromolecular layer corresponding to Tg1, a polymer layer corresponding to Tg2 and the second macromolecular layer corresponding to Tg3 (Final Office action, page 6). Still further, the Examiner states the polymer layer would be sandwiched in between the two macromolecular layers as instantly claimed since Otsuka, et al. teach the macromolecular layer must be in contact and adjacent to the polymer layer (Final Office action, page 6).

The Examiner relies on Patnode, et al. to teach the deficiencies of Otsuka, et al. The Examiner believes that it would have been obvious to one of ordinary skill in the art to combine the teachings of Otsuka, et al. and Patnode, et al. in order to utilize a third pressure sensitive layer (Final Office action, pages 6-7).

The Examiner proceeds to repeat the analysis of Otsuka, et al., but relies on Chien, et al. to also support the missing teachings of Otsuka, et al. It is argued by the Examiner that Chien, et al. teach a multilaminate device containing a first adhesive layer with a first drug which correlates to Otsuka, et al.'s macromolecular layer, a separating layer which correlates to Otsuka, et al.'s polymer layer and another adhesive layer containing a second drug, which correlates to Otsuka, et al.'s suggested second macromolecular layer. Therefore, the Examiner concludes that if one desired to utilize different drugs for combination therapy as known in the prior art, one would have been motivated to utilize another pressure sensitive adhesive macromolecular layer, which has a lower glass temperature than the polymer layer (Final Office action, pages 10-11).

Rejection of claims 33-43 under 35 U.S.C. 112, first paragraph

The applicant respectfully traverses the rejection on the basis that the term "or different" is new matter and submits that the original disclose clearly provides support for either of two instances: (1) where the system has three layers and the polymer of the first and third layers have the same Tg while the polymer of the second layer has a second Tg; and (2) where the system has three layers and all three layers have a polymer having a different Tg. The applicant agrees with the Examiner that the specification, namely Fig. 1, supports the configuration where the system has three layers and the polymer of the first and third layers have the same Tg, while the polymer of the second layer has a different Tg. However, the applicant also respectfully submits that the specification quite clearly supports the second Tg configuration as well. With reference to the specification, page 9, lines 1-2 recite "The various layers **differ** (emphasis added) in their glass transition temperature (Tg)." On page 10, lines 1-5, the specification clearly recites "...

at least two (emphasis added) polymer-containing layers upon one another, with the layers containing polymers which **differ** (emphasis added) in their glass transition temperature." Moreover, original claims 1 and 5 recite in part "...the polymers used for the different layers **differ** (emphasis added) in their glass transition temperature" and "...layers containing polymers that **differ** (emphasis added) in their glass transition temperature." Still further, the Abstract as filed recites in part "...**at least two** (emphasis added) polymer-containing layers, characterized in that the polymer used for the different layers **differ** (emphasis added) in their glass transition temperature."

The expression "at least two layers" (specification, page 6, last paragraph) implies that the laminate constituting the therapeutic system may comprise, for instance, three layers that contain polymers having different glass transition temperatures. In view of this general statement, one skilled in the art, when reading the description of Figure 1 (top of page 7 of the present specification), would not assume that Tg1 of matrix 1a and Tg1 of matrix 1b would have to be identical in each case. "At least two layers" means just that – two layers, three layers, etc. Furthermore, the formula "Tg2 > Tg1" generally indicates that the Tg of the polymer of the inner layer (matrix 2) should be higher than the Tg of the polymers of the outer layers (matrix 1a, 1b), but does not necessarily mean that the Tg of the respective outer layers must be identical. Although it may be advantageous for practical reasons to use outer layers having identical compositions (and Tg values) – as in the Example in the specification – this is not an absolute requirement according to any teaching of the present invention.

The Applicant also wishes to note that nowhere in the present specification is it recited that it is critical for Tg1 and Tg3 to be identical. The Applicant submits that the

main reason why this particular embodiment (where Tg1 and Tg3 are identical) was selected in the Example was due to practical reasons, as mentioned above, and is not intended to limit the invention to such a configuration. In other words, this particular configuration would typically be easier and more inexpensive to produce than a configuration where all the layers have different Tg's.

In light of the aforementioned passages of the present specification, the Applicant respectfully submits that the specification provides sufficient support for a system having three layers, where the first layer has a polymer with Tg1, the second layer has a polymer with Tg2 and the third layer has a polymer with Tg3 and where Tg1 and Tg3 may be different (or identical) and where Tg2 is greater than Tg1 and Tg3. The limitation "or different" is clearly supported by the specification and is not new subject matter. Withdrawal of this rejection is respectfully requested.

Rejection of claims 33-43 under 35 U.S.C. 103(a)

The Applicant respectfully traverses the rejection of claims 33-43 being obvious in light of the cited prior art. The Applicant first submits that, contrary to the Examiner's conclusion, Otsuka, et al. do not provide a clear teaching according to which it would be essential that the polymer of the polymer layer has a Tg that is higher than the Tg of the polymer of the macromolecular layer.

The Examiner refers to the glass transition temperatures taught by Otsuka, et al. in connection with the polymer layer and macromolecular layer and compares the same to the layers of the present invention. Otsuka, et al. indicate that the range for the polymer layer (which apparently corresponds to the layer Tg2 of the present invention) is somewhat higher than the range indicated by Otsuka, et al. for the macromolecular layer

(i.e., "not lower than -50°C" vs. "not lower than -70°C;" col. 2, line 24; col. 3, line 15, respectively). In light of this recitation of Otsuka, et al., the reference does not provide a clear teaching according to which it would be essential that the polymer of the polymer layer has a Tg that is higher than the Tg of the polymer of the macromolecular layer since the respective ranges provided by Otsuka, et al., as noted above, overlap. For example, example 3 (col. 8, line 10 – col. 10, line 25), which is in accordance with the invention set forth by Otsuka, et al., relates to a composition in which the skin-adhesive layer, which may be compared to the layer Tg1 of the present invention, has a Tg that is higher than the Tg of the macromolecular layer, which may be compared to the layer Tg2 of the present invention. Taking Otsuka, et al. in its entirety in accordance with M.P.E.P. §2141.02(VI), the reference clearly is vague on whether or not it is essential for the Tg of the polymer layer to be higher than the Tg of the macromolecular layer.

The applicant further submits that it is simply not clear to one skilled in the art whether Otsuka, et al. suggest more than two polymer layers, as argued by the Examiner on page 5, lines 19-20 of the Final Office action and repeated in the Advisory Action. Referring to column 2, lines 5-9 of Otsuka, et al., the preparation of Otsuka, et al. comprises "at least two layers, namely a (emphasis added) layer of a macromolecular substance ... and a (emphasis added) polymer layer." As a third or further layer, a supporting sheet may be provided (col. 2, lines 63-65; claim 11). However, Otsuka, et al. do not clearly suggest using a polymer layer (comprising a polymer with a Tg not lower than -50°C) as a third or further layer. In fact, Otsuka, et al. are quite clear that a third layer would actually be a film or sheet on one side of the polymer layer (col. 2, lines 63-65 provides "The above polymer is preferably supported, on one side thereof, by a film or

sheet substantially impermeable to the drug and adjuvant..."). Based on the Examples and the specification provided by Otsuka, et al., one skilled in the art would readily recognize that the preparation of Otsuka, et al. comprises a single macromolecular layer, a single polymer layer and a supporting sheet (and possibly a release liner (col. 6, line 20)).

According to Otsuka, et al., the macromolecular substance layer has the function of securing adhesion of the preparation to the skin (col. 3, lines 3-10). Otsuka, et al. does not teach or recite any other functions for this layer. Since a skin-adhesive medicinal preparation would require only a single adhesive layer for providing adhesion to the skin, Otsuka, et al. would not suggest the presence of a second macromolecular substance layer as this would be counter-intuitive to the teaching of Otsuka, et al. Contrary to the Examiner's assertion in the Advisory Action, Otsuka, et al. do not unambiguously teach "in particular at least one macromolecular layer."

The Examiner further supports her position by stating that on page 6, lines 1-2 of the Final Office action, Otsuka, et al. teach that the composite thereof contains "*at least* (emphasis provided) two layers and in particular *at least one* (emphasis provided) macromolecular layer." The Applicant strongly disagrees with this interpretation of Otsuka, et al. According to the teaching of Otsuka, et al., it is essential that the drug compound and the absorption-enhancing compound are present in different layers of the composite preparation (col. 6, lines 22-26). In accordance with this requirement, claim 1 of Otsuka, et al. specifies that "one of said layers (a) and (b) contains a ... drug and [the] other of said layers contains an adjuvant..." The passage of Otsuka, et al. in column 2,

lines 5-13 corresponds to this claim recitation and has the same meaning. Otsuka, et al. recites the following at column 2, lines 4-15:

> "[A] composition preparation characterized in that it comprises at least two layers, namely a layer of a macro-molecular substance having pressure-sensitive adhesiveness at ordinary temperatures and a polymer layer adjacent to said macromolecular substance layer, that at least one of the macro-molecular substance layer and polymer layer at least contains a percutaneously absorbable drug and the other at least contains an adjuvant capable of increasing percutaneous drug absorption, and that the drug and adjuvant respectively can migrate into the adjacent macromolecular substance layer and polymer layer."

The above recitation of Otsuka, et al. does not teach "at least one macromolecular layer," as alleged by the Examiner.

To the contrary, the Applicant respectfully submits that Otsuka, et al. teach:

1. that there are at least two layers;
2. one of these layers is a macromolecular polymer layer;
3. another of these layers is a polymer layer;
4. the macromolecular layer and the polymer layer are adjacent to each other;
5. at least one of the macromolecular layer and the polymer layer (e.g., the macromolecular layer) at least contains a percutaneously absorbable drug;
6. the other layer (e.g., the polymer layer) at least contains an adjuvant;
7. the polymer layer is supported on one side (i.e., the side not adjacent to the macromolecular layer) by a film or sheet (which is another layer of the "at least two layers"); and
8. the macromolecular layer may preliminarily include formation on a release liner followed by transfer of the macromolecular layer onto the polymer layer for lamination.

The teaching of Otsuka, et al. clearly does not include "at least one macromolecular layer," but rather just a single macromolecular layer.

The Applicant's position that Otsuka, et al. fail to teach "at least one" macromolecular layer is further supported by the fact that Otsuka, et al. discusses throughout the reference "a" (or "the") macromolecular layer (emphasis added), rather than "at least one macromolecular layer" or "macromolecular layers") (see for instance, col. 6, lines 10, 14, 17-18, 19-20; col. 7, lines 13-14; claim 1)). It should also be noted that Otsuka, et al., when describing the various embodiments and modifications of the invention, always recites "the macromolecular substance layer" and "the polymer layer" (col. 6, line 22 – col. 7, line 18) in the singular form. The Applicant believes that this demonstrates that Otsuka, et al. had not seriously considered the possibility of employing more than only one macromolecular substance layer.

The phrase "at least one of the macromolecular substance layer and polymer layer..." in Otsuka, et al. means that either the macromolecular substance layer or polymer layer (or both layers) at least contains a drug and the respective other layer at least contains an absorption-enhancing adjuvant. The underlying idea is that the drug and adjuvant are initially kept separately in two different layers. However, the Applicant believes that the phrase "at least one of the macromolecular substance layer and polymer layer ..." cannot and should not be interpreted as referring to more than one macromolecular substance layer. In other words, the wording of Otsuka, et al. ("at least one of the ...") is not the same as the Examiner's interpretation ("at least one macro layer"). Since Otsuka, et al. do not clearly and unambiguously teach "at least one macromolecular substance layer," this reference does not provide a clear suggestion that

more than one macromolecular layer may be used, as stated by the Examiner in the Office action (page 6, line 2; page 7, lines 21-22; page 9, line 21; page 11, lines 21-22).

Moreover, the Applicant submits that the wording "at least contains a drug" and "at least contains an adjuvant" (col. 2, lines 9-13) suggest that each of the two layers (the macromolecular layer and the polymer layer) may contain more than one drug or more than one adjuvant, or even contain multiple compounds, but regardless must contain at least one drug and the other at least one adjuvant. Therefore, even if one skilled in the art would have desired to incorporate a combination of two or more drugs into Otsuka's preparation, that person would have added these further substances to the respective layer in light of the teaching of Otsuka, et al. and would not have provided a third or further drug-containing or adjuvant-containing layer.

The Applicant still further respectively submits that if one were to assume that Otsuka, et al. does suggest using two macromolecular layers, the relative position of this second macromolecular layer and the Tg of the polymer contained in this layer would not at all be unambiguous to one skilled in the art. According to Otsuka, et al., the function of the macromolecular layer is to secure the adhesion of the preparation to the skin (col. 2, lines 6-7; col. 3, lines 3-6), as noted above. Therefore, there would not have been any motivation for a skilled person to have provided a second skin-adhesive layer at the opposite side of the polymer layer, as it would be unnecessary, disadvantageous and impractical to have a second skin-adhesive surface on a non-skin-contacting side.

Moreover, throughout Otsuka, et al. and as already noted above, the polymer layer is described as being covered by a support sheet on one side (i.e., on the side that is not in contact with the macromolecular layer); (col. 2, lines 63-65; Examples). Specifically,

Otsuka, et al. teach that "[t]he above polymer layer is preferably supported, on one side thereof (emphasis added), by a film or sheet substantially impermeable to the drug and adjuvant..." This still further supports the Applicant's position that this polymer layer was clearly not intended to be covered (or "sandwiched") by an additional adhesive macromolecular layer, as suggested by the Examiner in the Final Office action at page 8, lines 3-6). The placement of a second macromolecular layer on the other side of the polymer layer to "sandwich" the polymer layer therebetween would go against the specific teaching of Otsuka, et al. that a film or sheet (impermeable to the drug) is placed on one side of the polymer layer for support.

Moreover, the cited passage (col. 2, lines 5-10) of Otsuka, et al. relates to the case where the "composite preparation" comprises a polymer layer and a macromolecular layer. Therefore, this passage cannot teach anything about the location of a second macromolecular layer (whose presence is merely speculative anyhow) relative to the polymer layer. As noted above, the macromolecular substance – according to Otsuka, et al., col. 3, lines 3-10 – is required to provide skin-adhesiveness. However, providing skin-adhesive layers on each side of the polymer layer (i.e., sandwiched) would be inconsistent with the teachings of Otsuka, et al. Any "sandwiched" configuration of Otsuka, et al. would be the polymer layer "sandwiched" on one side by a macromolecular layer and on the other side by a film or sheet, as discussed above. The Applicant respectfully believes that the Examiner's conclusion that Otsuka, et al. teach a second macromolecular layer adjacent to the polymer layer is clearly inapposite to Otsuka, et al.'s preferred, clear and unambiguous teaching that a film or sheet substantially

impermeable to the drug and adjuvant be placed on one side of the polymer layer (col. 2, lines 63-65).

It may also be noted that Otsuka, et al.'s teaching that the polymer layer must be adjacent to the macromolecular substance layer can only be interpreted to mean that these two layers must not be separated by an impermeable layer which would impede the migration (diffusion) of the drug or adjuvant. This is an important requirement in order to enable the drug and adjuvant (which are present separately in the two layers) to migrate into the respective other layer, as explained in col. 2, lines 9-15 of Otsuka, et al. However, this passage (col. 2, lines 5-10) does not teach or recite anything about the location of an alleged further macromolecular substance layer. Even if an alleged second macromolecular substance layer would be present, this layer could be placed on top of the first macromolecular substance layer and the resulting composite preparation would still meet the requirement of a "polymer layer adjacent to said macromolecular substance layer," since the first macromolecular substance layer would still be adjacent to the polymer layer as required, and Otsuka, et al.'s criteria would still be satisfied. In other words, contrary to what was suggested by the Examiner, the criteria taught by Otsuka, et al. do not unambiguously suggest a "sandwich" configuration when the presence of an alleged further macromolecular substance layer is assumed.

Regarding the Tg of the macromolecular layer, the Applicant submits that the limitation provided in col. 3, lines 11-26 of Otsuka, et al., is preferred to improve the shape-holding property, to prevent residue on the skin, to prevent skin irritation and to improve skin adhesiveness (col. 3, lines 14-18). However, if a second macromolecular layer would be provided on the other side of the polymer layer (in a "sandwiched"

configuration, as alleged by the Examiner), then this polymer layer would be located opposite to the skin-contacting side of the composite preparation. Consequently, Tg ranges indicated in column 3 (of Otsuka, et al.) would ultimately be rendered inapplicable in this case. Clearly, one skilled in the art would have assumed that this Tg criterion must only be observed when the macromolecular layer is a skin contact layer. Therefore, even if one skilled in the art would have considered adding a second macromolecular substance layer in a sandwich-type configuration as suggested by the Examiner, it would not have been obvious to use a layer comprising a polymer whose Tg is lower than the Tg of the center layer (i.e., Tg2 in the present invention). In light of the numerous deficiencies of Otsuka, et al., withdrawal of this rejection is respectfully requeted.

As explained above, the Examiner cites Patnode, et al. for combining with Otsuka, et al. to teach a third layer and to utilize an additional pressure sensitive layer (layer 57 of Fig. 15 of Patnode, et al.). The applicant respectfully disagrees for at least the aforementioned deficiencies of Otsuka, et al. However, referring to Patnode, et al., the additional pressure sensitive layer 57 is functionally linked to the rate-controlling membrane 55 (Fig. 15). The multilaminate device is adhered to the skin by the adhesive surface of the pressure sensitive layer 56 that is covered by the release liner 58. The active substance present in pressure sensitive layer 57 migrates through membrane 55 and pressure sensitive layer 57 to produce a controlled migration of active substance towards the skin surface (col. 13, lines 1-28). Therefore, in the absence of a rate-controlling membrane, there would be no need or motivation for adding a second, active substance-containing adhesive layer 57.

Otsuka, et al. do not suggest that the preparations may contain a rate-controlling membrane. The function of the polymer layer is to allow diffusion and migration of a drug and adjuvant, not to restrict diffusion and migration (col. 2, lines 16-20). Hence, the polymer layer mentioned by Otsuka, et al. is not regarded as a rate-controlling membrane (as mentioned by Patnode, et al.). Therefore, as the second/additional adhesive layer disclosed by Patnode, et al. is linked to the presence of a rate-controlling membrane and performs a specific function together with this membrane, and since Otsuka, et al. do not even consider using a rate-controlling membrane, there would have been no motivation for one skilled in the art to have applied the teachings of Patnode, et al. with Otsuka, et al. to arrive at the present invention.

In light of the aforementioned deficiencies of the combination of teachings of Otsuka, et al. and Patnode, et al., the applicant respectfully submits that the combination of references fails to teach every limitation set forth in claims 33-43 and that due to these deficiencies, one skilled in the art would not have been motivated to combine these references to arrive at the present invention. Withdrawal of this rejection is strongly requested.

Turning now to the second rejection under Section 103(a), the applicant respectfully traverses and disagrees for at least the numerous aforementioned deficiencies of Otsuka, et al. To reiterate, Otsuka, et al. fails to teach or disclose at least one pressure-sensitive adhesive macromolecular substance layer. There would be no motivation to incorporate a "third" macromolecular pressure sensitive drug-containing layer. For the same reason, the applicant respectfully disagrees with the Examiner's conclusion (referring to Chien, et al.) that "another adhesive layer containing a second drug ...

correlates to Otsuka, et al.'s suggested second macromolecular layer." Regarding Tg values, as discussed above, Otsuka, et al. do not teach or suggest an additional macromolecular layer and if one skilled in the art would have considered the possibility of adding such an additional layer, he or she could not have relied on Otsuka, et al. for selecting a polymer having a suitable Tg value as required by the present invention. Likewise, Chien, et al. do not teach or suggest the Tg values of the polymers present in the adhesive layers. Therefore, the Applicant respectfully disagrees with the conclusion drawn by the Examiner that "one would have been motivated to utilize another pressure-sensitive adhesive macromolecular layer, which has a lower glass temperature than the polymer layer" (Office action, page 11, lines 9-11). It is clear that neither Otsuka, et al. or Chien, et al. suggest any teaching relating to the Tg of a putative additional pressure-sensitive adhesive layer.

The Examiner further states that "if a skilled artisan desired to provide a combination therapy wherein one device contained two different drugs, one would have been motivated to use two pressure-sensitive macromolecular layers wherein each respective layer would comprise a different drug" (Final Office action, page 12, lines 11-13). However, the two-layer composite preparations described by Otsuka, et al. may contain two or more drug substances within one of the layers, as discussed above (col. 2, lines 10-11 "...at least contains therein...;" col. 5, lines 51-52). Therefore, combination therapy could be provided simply by using a combination of active substances within (for instance) the pressure-sensitive macromolecular layer, in accordance with the teaching of Otsuka, et al., and there would be no need for adding a further layer in order to be able to provide a combination therapy.

In light of the deficiencies of the combination of the teachings of Otsuka, et al. and Chien, et al., the applicant respectfully submits that the combination of references fails to teach every limitation set forth in claims 33-43 and that due to these deficiencies, one skilled in the art would not have been motivated to combine these references to arrive at the present invention. As explained in the response to the Final Office action, one of the main objectives of the present invention is to reduce cold flow. It is stated in the "Summary of the Invention" of the present application that "...it is an object of the invention to provide a process for improving cohesion in order to achieve a clear reduction of cold flow..." Neither Otsuka, et al., nor Patnode, et al. or Chien, et al. are directed to this object or discuss it in any way. This is yet another reason that these references should not be relied upon to support a rejection of the present claims. Withdrawal of this rejection is strongly requested.

In the Advisory Action (second to last paragraph on the "attached sheet" of the Advisory Action), the Examiner states that the Applicant argues that "at least one" does not mean more than one and disagrees with the examiner's interpretation. This is not the case. The Applicant at no time set forth an argument that "at least one" does not mean more than one. To the contrary, the Applicant argued that, as discussed at great length above, Otsuka, et al. does not teach "at least two layers, namely at least one pressure-adhering macromolecular layer." Rather, the Applicant believes that Otsuka, et al. teaches "at least two layers, namely, a layer of a macro-molecular substance ... and a polymer layer adjacent to said macromolecular substance layer." (col. 2, lines 1-10 of Otsuka, et al.) and that this particular wording does not mean "at least one macromolecular substance layer."

SUMMARY

The Applicant respectfully submits that the cited references do not teach, suggest or show the present invention as presently claimed or advantages attendant thereto. In conclusion it is requested that the rejection of claims 33-43 as failing to comply with the written description requirement, as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) in view of U.S. Patent No. 6,063,838 (Patnode, *et al.*) under 35 U.S.C. §103(a) and as being unpatentable over U.S. Patent No. 5,151,271 (Otsuka *et al.*) in view of U.S. Patent No. 5,023,084 (Chien, *et al.*) under 35 U.S.C. §103(a) be withdrawn, that the Board reverse the decision of the Examiner and allow claims 33-43.

Respectfully submitted,

Date: April 20, 2006

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Enc. Appendix

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Appendix of Claims

1-32. (canceled)

33. (previously presented) A method for providing therapeutic applications in humane medicine, said method comprising the step of applying to living skin a therapeutically active substance-containing therapeutic system, the system comprising three polymer-containing layers, wherein;

a first layer comprises a polymer having a glass transition temperature (T_g1), a second layer comprises a polymer having a glass transition temperature (T_g2), and a third layer comprises a polymer having a glass transition temperature (T_g3), said first, second and third layers being laminated on top of each other such that said second layer is located between said first layer and said third layer and is directly connected to the first layer and to the third layer; and

wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different, wherein at least one of said three polymer layers contains at least one therapeutically active substance and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

34. (previously presented) An active substance-containing therapeutic system for application on the skin, said system comprising three polymer-containing layers, wherein;

a first layer comprises a polymer having a glass transition temperature (T_g1), a second layer comprises a polymer having a glass transition temperature (T_g2), and a third layer comprises a polymer having a glass transition temperature (T_g3), said first, second and third layers being laminated on top of each other such that said second layer is located between said first layer and said third layer and is directly connected to the first layer and to the third layer; and

wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different, wherein at least one of said three polymer layers contains at least one therapeutically active substance and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

35. (previously presented) The therapeutic system according to claim 34, wherein said system further comprises a backing layer and a protective layer.

36. (previously presented) The therapeutic system according to claim 34, wherein at least one of said polymer-containing layers comprises a high-molecular weight polymer having film-forming properties.

37. (previously presented) The therapeutic system according to claim 34, wherein at least one of said polymer-containing layers is formed and arranged as an active substance reservoir.

38. (previously presented) The therapeutic system according to claim 34, wherein at least one of said polymer-containing layers is formed to simultaneously serve as a control means for active substance release.

39. (previously presented) A process for manufacturing a therapeutic system according to claim 34, said process comprising the steps of laminating a first layer which comprises a polymer having a glass transition temperature (T_g1) onto a second layer for reducing cold flow in said system, said second layer comprising a polymer having a glass transition temperature (T_g2), and subsequently laminating a third layer on said second layer, said third layer having a polymer having a glass transition temperature (T_g3), wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different, wherein at least one therapeutically active substance is added to at least one of said layers and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

40. (previously presented) A method for providing therapeutic applications in humane medicine, said method comprising the step of applying to living skin a therapeutically active substance-containing therapeutic system, the system comprising three polymer-containing layers, wherein at least one of said polymer-containing layers is an active substance release rate-controlling layer, and wherein;

a first layer comprises a polymer having a glass transition temperature (T_g1), a second layer comprises a polymer having a glass transition temperature

(T_g2), and a third layer comprises a polymer having a glass transition temperature (T_g3), said first, second and third layers being laminated on top of each other such that said second layer is located between said first layer and said third layer and is directly connected to the first layer and to the third layer; and

wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different, wherein at least one of said three polymer layers contains at least one therapeutically active substance and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

41. (previously presented) A method for providing therapeutic applications in humane medicine, said method comprising the step of applying to living skin a therapeutically active substance-containing therapeutic system, the system comprising three polymer-containing layers, wherein;

a first layer comprises a polymer having a glass transition temperature (T_g1), a second layer comprises a polymer having a glass transition temperature (T_g2), and a third layer comprises a polymer having a glass transition temperature (T_g3), said first, second and third layers being laminated on top of each other such that said second layer is located between said first layer and said third layer and is directly connected to the first layer and to the third layer; and

wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different; and

wherein said polymer having a glass transition temperature (T_g1) and said polymer having a glass transition temperature (T_g2) are selected from the group consisting of polymers based on methacrylic acid and polymers based on polyacrylic acid esters, and said polymer having a glass transition temperature (T_g3) is selected from the group consisting of methacrylic acid esters; and

wherein at least one of said three polymer layers contains at least one therapeutically active substance and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

42. (previously presented) An active substance-containing therapeutic system for application on the skin, said system comprising three polymer-containing layers, wherein;

a first layer comprises a polymer having a glass transition temperature (T_g1), a second layer comprises a polymer having a glass transition temperature (T_g2), and a third layer comprises a polymer having a glass transition temperature (T_g3), said first, second and third layers being laminated on top of each other such that said second layer is located between said first layer and said third layer and is directly connected to the first layer and to the third layer; and

wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different; and

wherein said polymer having a glass transition temperature (T_g1) and said polymer having a glass transition temperature (T_g2) are selected from the group consisting of polymers based on methacrylic acid and polymers based on polyacrylic acid esters, and said polymer having a glass transition temperature (T_g3) is selected from the group consisting of methacrylic acid esters; and

wherein at least one of said three polymer layers contains at least one therapeutically active substance and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

43. (previously presented) A method for providing therapeutic applications in humane medicine, said method comprising the step of applying to living skin a therapeutically active substance-containing therapeutic system, the system comprising three polymer-containing layers, wherein at least one of said polymer-containing layers is an active substance release rate-controlling layer, and wherein;

a first layer comprises a polymer having a glass transition temperature (T_g1), a second layer comprises a polymer having a glass transition temperature (T_g2), and a third layer comprises a polymer having a glass transition temperature (T_g3), said first, second and third layers being laminated on top of each other such that said second layer is located between said first layer and said third layer and is directly connected to the first layer and to the third layer; and

wherein T_g2 is greater than T_g1 and T_g3, and the glass transition temperature T_g1 of the polymer of said first layer and the glass transition temperature T_g3 of the polymer of said third layer are identical or different; and

wherein said polymer having a glass transition temperature (T_g1) and said polymer having a glass transition temperature (T_g2) are selected from the group consisting of polymers based on methacrylic acid and polymers based on polyacrylic acid esters, and said polymer having a glass transition temperature (T_g3) is selected from the group consisting of methacrylic acid esters; and

wherein at least one of said three polymer layers contains at least one therapeutically active substance and wherein said glass transition temperatures of said layers improve cohesion of said system for reducing cold flow in said system.

Evidence Appendix

I. U.S. Patent No. 5,151,271 (Otsuka, et al.)

II. U.S. Patent No. 6,063,838 (Patnode, et al.)

III. U.S. Patent No. 5,023,084 (Chien, et al.)

IV. Figure 1 of the present specification

V. M.P.E.P. §2141.02(VI)

Related Proceedings Appendix

None.

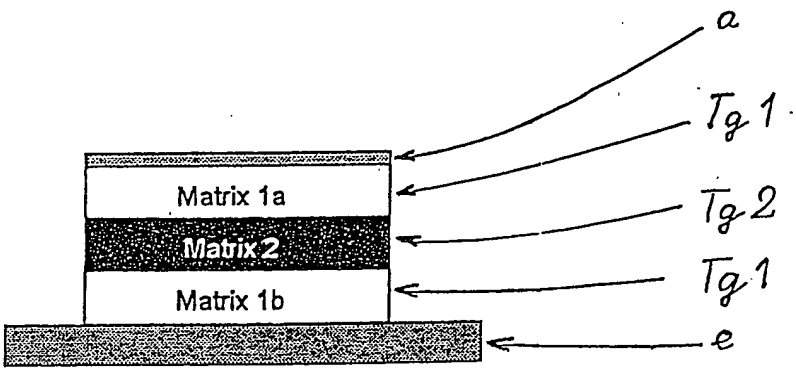

FIG. 1

EXHIBIT

IV

VI. < PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.).

>However, "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).<